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FEB - 9 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: October 14, 2011

1. Company and Correspondent making the submission:

Name – Shanghai 3F Electronics Co., Ltd.
Address – 77325 Joyce Way
Echo, Oregon 97826
Telephone – 931-625-4938
Fax – 541-376-5063
Contact – Charles Mack
Email – charliemack@irc-us.com

2. Device :

Trade/proprietary name: PMS8210A (IRIS) Multi-Parameter Patient Monitor
Model Code 500

Common Name : Multi-parameter Patient Monitor

Classification of the device: Class II
Panels: Cardiovascular, General Hospital, Anesthesiology
Product code: 21CFR870.2300, Monitor, Physiological, MWI

Establishment Registration Number : 3008383116

Predicate Devices:

Predicate Model	Manufacturer	K Number	Submitted Device
PMS8210A (Iris) Patient Monitor/ Multi-Parameter Patient Monitor	Shanghai 3F Electronics Co., Ltd.	K100394	PMS8210A Model Code 500 (Iris) Patient Monitor/ Multi-Parameter Patient Monitor

3. Description :

3.1 General

PMS8210A Model Code 500 Patient Monitor is a battery or line-powered patient monitor. The Patient Monitor acquires the physiological signals such as ECG, respiration (RESP), Non-Invasive blood pressure (NIBP), Saturation of pulse oxygen (SPO2), Temperature (TEMP), End-tidal ($etCO_2$). The signals are converted into digital data and processed, examines the data for alarm conditions and displays the data. The monitor also provides operating control for the user. The submitted device is the same as the predicate with two differences. The new model has added an $etCO_2$ function and the Temp module has been changed. The new Temp module is a previously FDA cleared device.

The patient monitor is intended to be used in a hospital clinical area such as intensive care units, cardiac care units, operation room, emergency department, to provide additional information to the medical and nursing staff about the physiological condition of the patient. The PMS8210A Model Code 500 patient monitor is intended to be used only under regular supervision of clinical personnel. The intended location of use is clinics.

4. Indication for use :

PMS8210A Model Code 500 is a multi-parameters monitor used on human patients. The target populations are adult, pediatric and neonatal patients. The PMS8210A Model Code 500 has certain features and functions.

The patient parameters that can be monitored by PMS8210A Model Code 500 are: ECG(3-lead or 5-lead selectable), Heart Rate(HR), Pulse Rate(PR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Arterial Hemoglobin Oxygen Saturation(SpO2), Temperature (TEMP) and End-tidal CO2 (EtCO2) . Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The PMS8210A Model Code 500 is intended for use in a health care facility setting. It is intended for use by qualified medical personnel trained in the use of the equipment.

The PMS8210A Model Code 500 is not recommended for use in a patient's home or residence, or when it has not been ordered by a physician.

5. Comparison with predicate device: - Please see next page for the comparison table.

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Table of Comparison to Predicate Device

1. General Specifications (i.e. physical/electrical)

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor, Model code 500	PMS8210A Multi-parameter Patient Monitor(K100394)
Manufacturer	Shanghai 3F Electronics Co., Ltd.	Shanghai 3F Electronics Co., Ltd.
510(K) Number:	N/A	K100394
Physical dimension/weight	Same	Dimensions: 250 (W)×180 (H)× 180 (D) (mm) Weight : 2.0kg
Display	Same	7 segment LED + 3.2" colorful TFT LCD (320×240)
Button	Same	keys – front panel
Type, Degree of protection against electric shock	Same	AC power adapter Electr. Class Ⅰ and internal power supply
Power supply	Same	100～240VAC(±10%), 50/60Hz(±3Hz),45VA
Internal power source	Same	Insetting sealed lithium batter：2200mAh and 4400mAh
Battery charging indicator	Yes	Yes
Low battery indicator	Yes	Yes
Battery charge time, typ.	Same	2200mAh : approx. 3 hours 4400mAh : approx. 6 hours
Flammable anesthetics	Same	not suitable
Operating condition	Same	Temperature: 0°C to 40°C (32°F to 104°F) Relative Humidity: ≤95%(non-condensing)
Storage condition	Same	Temperature: - 40°C to 55°C (-40°F to 131°F) Relative Humidity: ≤95% (non-condensing)
EMC	Same	IEC 60601-1-2:2007
Power on self test	Yes	Yes
Optional printer	Yes	Yes

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2. Non-Invasive Blood Pressure (NIBP): No change in NIBP

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor, Model code 500	PMS8210A Multi-parameter Patient Monitor(K100394)
NIBP module	Same	SUNTECH NIBP
Method	Same	Oscillometric
Patient type	Same	Neonatal, pediatric and adult patients
Unit of measure	Same	mmHg & kPa
Pressure measurement range – Systolic	Same	Adult: 40 ~ 260mmHg pediatric: 40 ~ 160mmHg Neonate: 40 ~ 130mmHg
Pressure measurement range – Diastolic	Same	Adult: 20 ~ 200mmHg pediatric: 20 ~ 120mmHg Neonate: 20 ~ 100mmHg
Pressure measurement range-Dean pressure	Same	Adult: 26 ~ 220mmHg pediatric: 26 ~ 133mmHg Neonate: 26 ~ 110mmHg
BP accuracy	Same	Arithmetic mean values:±5 mmHg; Standard deviation no greater than 8 mmHg.
BP measurement accuracy	Same	ANSI/AAMI SP10:2002; EN1060-4
Cuff pressure range	Same	0 to 300mmHg
Auto zero CAL	Yes	Yes
Over pressure protector	Same	Adult/ Pediatric: 300mmHg; Neonate: 150mmHg
Alarm setup	Same	The range is the same as parameter measurement range of SYS、DIA、MAP
Alarm method	Same	Sound light alarm, and record the alarm status for review

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3. Pulse Oximetry (SpO2) - No change in SpO2

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor, Model code 500	PMS8210A Multi-parameter Patient Monitor(K100394)
SpO2 module	Same	Nellcor SpO2
Patient type	Same	Adult, Pediatric & Neonate
SpO2 measurement range	0 ~ 100%	0 ~ 100%
SpO2 measurement accuracy	Same	adult/ Pediatric: 70~100%: ±2%; 0~69%: Unspecified. neonate 70~100%: (3%; 0~69%: Unspecified.
Alarm range(%)	Same	0~100%
Pulse rate measurement range	Same	20~250bpm
Pulse rate accuracy	Same	±3bpm (Geostationary) Or ±5 bpm (Campaign)
Alarm range–Pulse rate (bpm)	Same	20~250bpm

4. Temperature (Predictive & Monitor) – new device uses the new 510K Cleared TEMP module to replace the previous TEMP module

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor, Model code 500	PMS8210A Multi-parameter Patient Monitor(K100394)
510(K) Number:	K011059 (new TEMP module)	K100394
Measurement means	Infrared	Thermal
Patient type	Same	Adult, Pediatric & Neonate
Unit of measure	Same	°C & °F
Measurement site	Same	Oral, Rectal & Axillary
Temperature measurement range	Same	0°C~50°C (32~122°F)

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Temperature measurement accuracy	Same Same	±0.1°C (±0.2°F) ASTM E1112:00
Probe cross contamination control	Same	Single use Disposable cover

5. ETCO2 (Predictive & Monitor) – new device use the new 510K Cleared ETCO2 module

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor, Model code 500	PMS8210A Multi-parameter Patient Monitor(K100394)
510(K) Number	K081601	K100394
ETCO2 Measurement	Yes	No

6. ECG (Predictive & Monitor) - No change in ECG

Characteristics	Subject Device	Claimed SE Device 510(K) No.
Name and model	PMS8210A Multi-parameter Patient Monitor, Model code 500	PMS8210A Multi-parameter Patient Monitor
Lead	Same	3lead(RA,LA,LL); 5lead(RA,RL,LA,LL,V)).
Lead option	Same	Monitor lead(3 lead) / standard lead(5 lead)
Gain	Same	×0.5; ×1.
Sweep speed	Same	12.5mm/s, 25mm/s, 50mm/s
Range of heart rate monitoring	Same	Adult: 20~300 bpm; Neonate/ Pediatric: 20~350 bpm
Resolution	Same	1 bpm
Precision	Same	20～200 bpm: 5% or ±5bpm; 201～350 bpm: 10%.
Alarm setting	Same	The limit of alarm (setup range : 20~350 bpm), and leads-off alarm display.
Input resistance	Same	≥5 MΩ
CMRR	Same	≥89 dB
Heart disorder analysis	Same	NO

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Anti-polarized voltage	Same	≤±500 mV
Baseline renewing time	Same	<5 s after the defibrillation
ECG mode	Same	Mode 1 (Monitoring mode), mode 2(Monitoring mode), mode 3 (Surgical mode)
Frequency characteristic	Same	Mode 1 : 0.1Hz-40Hz; Mode 2 : 0.67Hz-40Hz Mode 3 : 1Hz-25Hz
Safeguard	Same	4000V high voltage isolation, anti-defibrillation

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Performance Standards:

No.	Category	Directives/Standards	Title and Comments
1	General	93/42/EEC	Medical Device Directive
		21CFR820	Code of Federal Regulations
		91/157/EEC	Battery Declaration Directive
		93/86/EEC	Battery Disposal Directive
		IEC60601-1:1988 A1:1991,+ A2:1995	General requirements for Safety and Essential Performance
		IEC60529	Water Ingress Testing (IPX 0)
		IEC60601-1-1:2000	Medical electrical equipment -- Part 1: General requirements for safety- Collateral standard-Safety requirements for medical electrical systems
		IEC60601-1-4:2000	Programmable medical systems
		IEC 60601-1-6:2006	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability

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No.	Category	Directives/Standards	Title and Comments
3	NIBP	IEC 80601-2-30:2009	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
		ISO 81060-2:2009	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
4	SPO_2	EN 865:1997	Pulse oximeters, 5 SpO_2 Particular requirements
		ISO 9919:2005	Medical electrical equipment --- Part 2-34: Particular requirements for the basic safety and essential performance of pulse oximeters equipment for medical use
5	Temperature	ASTM E1112:2000	Electronic thermometer for intermittent determination of patient temperature
		ASTM E1104-03	Standard Specification for Clinical Thermometer Probe Covers and Sheaths
		EN 12470-4:2000	Clinical thermometers-Part 4: Performance of electrical thermometers for continuous measurement.
6	Respiratory Measurement		

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Testing Performed

No.	Category	Directives/Standards	Title and Comments
7	ECG Measurement	ANSI/AAMI EC11:1991/(R)2001	Diagnostic electrocardiographic devices
		AAMI/ANSI EC13:2002/(R)2007	Cardiac monitors, heart rate meters, and alarms
		ANSI/AAMI EC I2:2000/(R) 2005	Disposable ECG electrodes
		AAMI EC53/(R) 2001	ECG cables and leadwires. (Cardiovascular)
8	EMC	IEC60601-1-2:2007	Medical Electrical Equipment-Part 1-2:General Requirements for Safety - 2.Collateral Standard-Electromagnetic compatibility - Requirements and tests
		IEC61000-3-2	Harmonic Emission
		EC61000-3-3	Voltage Fluctuations/Flicker Emission
		IEC61000-4-2	Electrostatic Discharge (ESD)
		IEC61000-4-3	Radiated RF electromagnetic field
		IEC61000-4-4	Electrical fast Transient/Burst (EFT)
		IEC61000-4-5	Surge current
		IEC61000-4-6	Conducted disturbances, induced by RF field
		IEC61000-4-8	Power frequency (50/60Hz) Magnetic field
		IEC61000-4-11	Voltage dips, short interruptions, and voltage variation on power supply input lines
		CISPR 11, EN55011	RF emissions

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No.	Category	Directives/Standards	Title and Comments
9	$etCO_2$	EN ISO 21647:2004	Particular requirements for the basic safety and essential performance of respiratory gas monitors
		EN 864:1996	Performance and safety requirements for Capnometers
		EN ISO 5356-1:2004	Anesthetic and respiratory equipment. Conical connectors Part 1: Cones and sockets
10	Biocompatibility	ISO10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing
11	Labeling	EN1041:1998	Terminology, symbols and information provided with medical devices - information supplied by the manufacturer with medical devices.
12	Marking	IEC60878, EN980, ISO7000, EN60417-1, EN60417-2	Graphical Symbols for use in the labeling of Medical Devices
13	Packaging	ISTA: Pre-Shipment Test Procedures (Procedure 1A, 1994 Rev.)	Pre-Shipment Test Procedures (Package)
14	Reliability	IEC60068-2-1	Environmental testing - Part 2-1: Tests - Test A: Cold
		IEC60068-2-2	Environmental testing - Part 2-2: Tests - Test B: Dry heat

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No.	Category	Directives/Standards	Title and Comments
14	Reliability	IEC 60068-2-6	Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal)
		IEC 60068-2-27	Environmental testing - Part 2-27: Tests - Te st Ea and guidance: Shock
		IEC60068-2-30	Environmental testing- Part 2-30: Tests - Tes t Db: Damp heat, cyclic
		IEC 60068-2-64	Environmental testing - Part 2-64: Tests - Te st Fh: Vibration, broadband random and guid ance
		IEC60529	Water Ingress Testing

7. Safety and Performance Data :
   Please refer to the Declaration of Conformity for the comprehensive list of testing performed on the PMS8210A Model Code 500 Multi-parameter Patient Monitor. The PMS8210A Model Code 500 has undergone Third Party safety testing in accordance with IEC standards and completed performance testing in accordance with IEC standards. In that this device has software of Moderate concern; the appropriate level of Software evaluation was performed.

8. Conclusions:
   In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Shanghai 3F Electronics Co., Ltd. concludes that the Patient Monitor, Model PMS8210A Model Code 500, is safe and effective and substantially equivalent to predicate devices as described herein.

9. Shanghai 3F Electronics Co., Ltd .will update and include in a summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shanghai 3F Electronics Co., Ltd.
c/o Charlie Mack
Principal Engineer
77325 Joyce Way
Echo, Oregon 97826

FEB - 9 2012

Re: K113183
Trade/Device Name: PMS8210A (IRIS) Multi-Parameter Patient Monitor, Model Code 500
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor
Regulatory Class: Class II (two)
Product Code: MWI
Dated: December 30, 2011
Received: January 10, 2012

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: PMS8210A (IRIS) Multi-parameter Patient Monitor, Model code 500

Indications for Use:

PMS8210A Model Code 500 is a multi-parameters monitor used on human patients. The target populations are adult, pediatric and neonatal patients. The PMS8210A Model Code 500 has certain features and functions.

The patient parameters that can be monitored by PMS8210A Model Code 500 are: ECG(3-lead or 5-lead selectable), Heart Rate(HR), Pulse Rate(PR), Respiration Rate(RESP), Non-invasive Blood Pressure (NIBP), Arterial Hemoglobin Oxygen Saturation(SpO2), Temperature (TEMP) and End-tidal CO2 (EtCO2) . Its design allows the operator to adjust the settings of parameter alarms that audibly and visually notify the operator when an excursion occurs.

The PMS8210A Model Code 500 is intended for use in a health care facility setting. It is intended for use by qualified medical personnel trained in the use of the equipment.

The PMS8210A Model Code 500 is not recommended for use in a patient's home or residence, or when it has not been ordered by a physician.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K113183